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DATE MAILED: 06/14/2006

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,901	02/10/2004	Michel Pairet	1/1175-1-C1	1193
28501	7590 06/14/2006		EXAMINER	
MICHAEL P. MORRIS			HAGHIGHATIAN, MINA	
BOEHRINGE	R INGELHEIM CORPO	RATION		
900 RIDGEBURY ROAD			ART UNIT	PAPER NUMBER
P. O. BOX 368			1616	
DIDCEFIELD	CT 06877-0368			

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/775,901	PAIRET ET AL.			
Office Action Summary	Examiner	Art Unit			
	Mina Haghighatian	1616			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONED	I. ely filed the mailing date of this communication. O (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on					
2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This	action is non-final.				
3) Since this application is in condition for allowar	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.			
Disposition of Claims					
4) ☐ Claim(s) 1 and 5-50 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1 and 5-50 are subject to restriction a	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examine	r.				
10) The drawing(s) filed on is/are: a) acce		Examiner.			
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correct	ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori	s have been received. s have been received in Application ity documents have been received I (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachment(s)	□	(770.440)			
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)         Paper No(s)/Mail Date     </li> </ol>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

### **DETAILED ACTION**

### Election/Restrictions

#### Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1, 5-22 and 45, drawn to formulations in powder form, classified in class 424, subclass 46.
- II. Claims 23-44, 46-47, drawn to propellant-containing solution or suspensions, classified in class 424, subclass 45.
- III. Claims 48-50, drawn to method of treating, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related formulations. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, dry powder formulations of Group I and propellant-containing solution or suspension of Group II are distinct and have do not overlap in scope. Dry powder formulations typically do not require propellants and use different devices for administration. They also require no or different carrier materials than solution formulations.

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Inventions I or II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the formulations of Group I or Group II can be used to treat different disorders and the disorders recited in claims 48-50 can be treated using different medicament or combinations of medicaments.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

## Election

This application contains claims directed to the following patentably distinct species:

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Claims 8-11 contain various active agents as dopamine agonists. A single agent or one Markush group of claims 8-11 should be elected for examination.

For examination purposes, Applicant is requested to elect a <u>single</u> disclosed species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

A telephone call was made to Ms. Wanda Petka on 06/07/06 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete **must** include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian June 08, 2006

> Johann Richter, Ph.D. Esq. Supervisory Patent Examiner Technology Center 1600